

REMARKS

Claims 1, 16, and 19 are pending.

Claims 2-15, 17-18, and 20 are canceled.

Claims 21-27 are new.

In the Advisory Action of September 15, 2004, the Examiner states that the then pending claim 1 recited an inducible promoter region that comprises a promoter and a coding sequence for a regulatory protein. The Examiner stated that promoter regions do not contain coding sequences and therefore claim 1 was indefinite under 35 U.S.C. 112, 2nd paragraph. In response, Applicant has clarified claim 1 by amendment and requests that the Examiner withdraw the 35 USC 112, second paragraph rejection.

In the Advisory Action of September 15, 2004, the Examiner maintains the 35 USC 112, first paragraph rejections set forth in detail in the November 6, 2002 Office Action. The Examiner asserts that specification lacks enablement for “any plant transformed with a DNA construct comprising any chemically induced promoter operably linked to a DNA coding sequence for invertase or a method of increasing yield in any plant transformed with the alcA/alcR switchable promoter sequence operably linked to any gene.” On page 3 of the November 6 Office Action, the Examiner further asserts that there is only one exemplified plant species set forth in the specification, and as a result, a claim directed to increasing the yield of any plant is not enabled.

Applicant respectfully disagrees. First, with regard to enablement of plant species in general, the specification describes the method of the present invention increasing the yield of a tobacco and a potato plant. These two plants are morphologically and physiologically distinct. Figure 4 shows that plant fresh weight and plant height is increased in tobacco lines expressing invertase when using a constitutive promoter, provided the promoter is activated by application of an external chemical inducer at selected times during the plant development. Figure 18 shows that chemically induced invertase expression in the potato tubers leads to an increase in total tuber yield. Therefore, the subject specification does in fact describe the successful use of the constructs of the invention in two disparate plant species.

It is respectfully submitted that the specification is sufficient to enable Applicant's claimed invention under applicable legal standards. The Manual of Patent Examining Procedure (MPEP) at 216408(a) refers to *In re Goodman*, 11 F.3D 1046 (Fed. Cir. 1993) to illustrate that a specification that discloses a method for producing mammalian peptides (in general) in dicot plants only, does not enable producing mammalian peptides in monocot plants. However, it is important to note that the patent application filing date in that case was July 1985. At that time, the transformation of monocot plants was highly unpredictable. In significant contrast, the present application was filed on August 8, 2000 and at that time genetic recombinant and biotechnological techniques were common procedures in the art, especially with regard to transformation and genetic manipulation of very distinct plant species, such as dicot and monocot plants. Further, in significant contrast to the facts of *In re Goodman*, Applicant's present specification discloses the successful transformation of two distinct plant species resulting in increased yield for each. The court in *In re Wands* ruled that the PTO had erred in rejecting the applicant's claim to immunoassay methods using a specified generic class of antibodies. The court ruled that the specification was enabled as those skilled in the monoclonal art could, using the state of the art and applicant's written disclosures, produce and screen other hybridomas secreting other antibodies falling within the generic without undue experimentation. Likewise, in this case, those skilled in the genetic recombinant art, using the state of the art and applicant's written disclosures, could transform plants of different species with a DNA sequence that codes of invertase, wherein the invertase is operatively linked to an inducible promoter system. Thus, given the Examples provided in the subject specification and the skill in the art, Applicant respectfully submits that it is not required to present additional Examples to enable the scope of the present claims.

The Examiner also states that the claims are not enabled for "a method of increasing yield in any plant transformed with the alcA/AlcR switchable promoter sequence operably linked to any gene..." Applicant has amended claim 1 such that the alcA promoter is linked to the invertase gene and not to "any gene."

The Examiner further states that the specification is not enabled for any chemically induced promoter. To support this argument, the examiner cites the results reported by Bussis et al. (Planta (1997) 202:126-36 and Sonnewald et al. Plant J. (1991) 1:95-106), which demonstrate that the constitutive expression of invertase in potato and tobacco leaves decreases

photosynthesis, as measured by a reduction in Rubisco activation state and CO₂ assimilation rate. The Examiner further states in the September 15, 2004 advisory action that Applicant did not address the examiner's remarks with respect to CAM and C4 plants with Kranz anatomy. Applicant has reviewed the file history. CAM and C4 plants with Kranz anatomy were raised by the examiner in the November 6, 2002 Office Action. Applicant has searched the Bussis and Sonnewald references and could find no reference to CAM and C4 plants with Kranz anatomy. Applicant respectfully requests that the Examiner explain in more detail its arguments relating to these concepts so that the Applicant can fully respond. Applicant has amended the claims to include invertase operably linked to an alcA promoter and optionally operably linked to a transcription terminator; and a DNA sequence encoding the alcR regulatory protein. Applicant respectfully submits that this amendment overcomes Examiner's 35 USC 112 rejection relating to "any chemically induced promoter."

The claims also stand rejected under 35 USC 103(a) as being unpatentable over Willmitzer in view of Caddick. The Examiner takes the position that Willmitzer teaches "transforming potato plants with an expression cassette having the class I patatin promoter operatively linked to a DNA sequence expressing an invertase, containing the coding sequence for a functional protein II signal peptide signal sequence, and regenerating a transformed potato plant (column 15, claims 5 and 8)." (Office Action, 04/09/2002) The Examiner cites Caddick for teaching the limitation of using the "inducible promoter such as alcA in conjunction with the alc/R gene under control of a promoter selected for a particular tissue to control gene expression both spatially and temporally to increase yield (see page 1, lines 15-27 of the 11/06/2002 Office Action) and thus provides motivation to optimize the yield in potato transformed with invertase as taught by Willmitzer."

Applicant respectfully submits that one skilled in the art would find no teaching, suggestion, or motivation to combine the Willmitzer and Caddick references. The Willmitzer reference describes expression of invertase using the class I patatin promoter, wherein the promoter is switched on throughout tuber development. The method described by the Willmitzer reference results in increased tuber yield. Clearly, there is no suggestion in this reference to use the additional and substantial step of applying a chemical inducer to a plant to switch on a promoter as described by Caddick. Likewise, the Caddick reference does not teach that its method would improve the potato tuber yield already enhanced using the method disclosed in the Willmitzer reference. In fact,

the Caddick reference, in view of the Willmitzer reference, is likely to suggest to one skilled in the art that applying an external chemical inducer to limit the level and time of target gene expression would limit tuber yield or at least be an unnecessary step in enhancing yield. Therefore, Applicant respectfully submits that the two references actually conflict. "A reference will teach away if it suggests that the line of development flowing from the references disclosure is unlikely to be productive of the result sought by the applicant." *In re Gurley* 27, F.3d 551, 553 (Fed. Cir. 1994). In *Winner International Royalty Corp. v. Wang*, 203 F.3d 1340 (Fed. Cir. 2000), the court ruled that to find obviousness based on a combination of references, the combination must be "desirable" not merely "feasible." In this case, although it is feasible to combine the Willmitzer and Caddick references, based on their disclosures, it would not be desirable. In view of the above remarks, Applicant respectfully submits that the two references do not make the present claimed invention obvious and requests that the Examiner withdraw his rejection under 35 USC 103.

In view of the above amendments and remarks, it is respectfully submitted that the application is ready for allowance. If any additional information is needed, the Examiner is invited to call the undersigned attorney at (919) 541-8614.

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Respectfully submitted,



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